

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

10/510912
DT04 Rec'd PCT/PTO 08 OCT 2004

Applicants: Flores, Osvaldo A. et al.

Serial No. To Be Assigned

Filed: On Even Date Herewith

For: HEPATITIS C VIRUS ASSAY SYSTEMS

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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MERCK & CO., INC.

By _____ Date _____

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5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

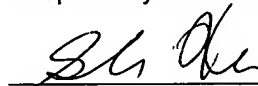
RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Sheldon O. Heber

Attorney _____ For Applicant(s)

Reg. No. 38,179

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Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-1958

Date: October 8, 2004

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
			Application Number	07510912	
			Filing Date		
			First Named Inventor	Flores, Osvaldo A. et al.	
			Group Art Unit		
			Examiner Name		
Sheet	2	of	4	Attorney Docket Number	21080P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Alter, H. "To C or Not To C: These Are the Questions", Blood, 1995, Vol. 85, pp. 1681-1695
		Ambler, R. "The structure of β -lactamases", Phil. Trans. R. Soc. Lond. B. Biol. Sci., 1980, Vol. 289, pp. 321-331
		Bartenschlager, R. et al. "Nonstructural Protein 3 of the Hepatitis C Virus Encodes a Serine-Type Proteinase Required for Cleavage at the NS3/4 and NS4/5 Junctions", Journal of Virology, 1993, Vol. 67, pp. 3835-3844
		Behrens, S. et al. "Identification and properties of the RNA-dependent RNA polymerase of hepatitis C virus", The EMBO Journal, 1996, Vol. 15, pp. 12-22
		Blight, K. et al. "Efficient Initiation of HCV RNA Replication in Cell Culture", Science, 2000, Vol. 290, pp. 1972-1974
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		Hijikata, M. et al. "Proteolytic processing and membrane association of putative nonstructural proteins of hepatitis C virus", Proc. Natl. Acad. Sci. USA, 1993, Vol. 90, pp. 10773-10777

Examiner Signature	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<p>Substitute for form 1449B/PTO</p> <p>INFORMATION DISCLOSURE</p> <p>STATEMENT BY APPLICANT</p> <p><i>(use as many sheets as necessary)</i></p>				COMPLETE IF KNOWN	
				Application Number	107510912
				Filing Date	
				First Named Inventor	Flores, Osvaldo A. et al.
				Group Art Unit	
				Examiner Name	
Sheet	3	of	4	Attorney Docket Number	21080P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Honda, M. et al. "Structural Requirements for Initiation of Translation by Internal Ribosome Entry within Genome-Length Hepatitis C Virus RNA", <i>Virology</i> , 1996, Vol. 222, pp. 31-42
		Iwarson, S. "The natural course of chronic hepatitis C", <i>FEMS Microbiology Reviews</i> , 1994, Vol. 14, pp. 201-204
		Kadonaga, J. et al. "The Role of the β -Lactamase Signal Sequence in the Secretion of Proteins by <i>Escherichia coli</i> ", <i>The Journal of Biological Chemistry</i> , 1984, Vol. 259, pp. 2149-2154
		Kew, M. "Hepatitis C virus and hepatocellular carcinoma", <i>FEMS Microbiology Reviews</i> , 1994, Vol. 14, pp. 211-219
		Kolykhalov, A. et al. "Hepatitis C Virus-Encoded Enzymatic Activities and Conserved RNA Elements in the 3' Nontranslated Region Are Essential for Virus Replication In Vivo", <i>Journal of Virology</i> , 2000, Vol. 74, pp. 2046-2051
		Kolykhalov, A. et al. "Identification of a Highly Conserved Sequence Element at the 3' Terminus of Hepatitis C Virus Genome RNA", <i>Journal of Virology</i> , 1996, Vol. 70, pp. 3363-3371
		Kuo, G. et al. "An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis", <i>Science</i> , 1989, Vol. 244, pp. 362-364
		Lohmann, V. et al. "Biochemical and Kinetic Analyses of NS5B RNA-Dependent RNA Polymerase of the Hepatitis C Virus", <i>Virology</i> , 1998, Vol. 249, pp. 108-118
		Lohmann, V. et al. "Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation", <i>Journal of Virology</i> , 2001, Vol. 75, pp. 1437-1449
		Lohmann, V. et al. "Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line", <i>Science</i> , 1999, Vol. 285, pp. 110-113
		Mizushima, H. et al. "Analysis of N-Terminal Processing of Hepatitis C Virus Nonstructural Protein 2", <i>Journal of Virology</i> , 1994, Vol. 68, pp. 2731-2734
		Pawlotsky, J. "Hepatitis C virus (HCV) NS5A protein: role in HCV replication and resistance to interferon- α ", <i>Journal of Viral Hepatitis</i> , 1999, Vol. 6, Suppl. 1, pp. 47-48
		Pietschmann, T. et al. "Characterization of Cell Lines Carrying Self-Replicating Hepatitis C Virus RNAs", <i>Journal of Virology</i> , 2001, Vol. 75, pp. 1252-1264
		Simmonds, P. "The origin and evolution of hepatitis viruses in humans", <i>Journal of General Virology</i> , 2001, Vol. 82, pp. 693-712
		Takamizawa, A. et al. "Structure and Organization of the Hepatitis C Virus Genome Isolated from Human Carriers", <i>Journal of Virology</i> , 1991, Vol. 65, pp. 1105-1113

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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COMPLETE IF KNOWN**Application Number**

10 / 510912

Filing Date**First Named Inventor**

Flores, Osvaldo A. et al.

Group Art Unit

Examiner Name

Sheet

4

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Attorney Docket Number

21080P

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